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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/870,392	05/30/2001	Steffen Lav	NN-5595.210 US	7486
7590	03/24/2006		EXAMINER	
Patent Department Skadden, Arps, Slate, Meagher & Flom LLP Four Times Square New York, NY 10036-6522			WILLIAMS, CATHERINE SERKE	
			ART UNIT	PAPER NUMBER
			3763	
DATE MAILED: 03/24/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	09/870,392	LAV ET AL.	
	Examiner Catherine S. Williams	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 08 February 2006.

2a) This action is FINAL.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 11-31 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 11-31 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 3/12/02

4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_

5) Notice of Informal Patent Application (PTO-152)

6) Other: \_\_\_\_\_

## DETAILED ACTION

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Specifically, the application does not set forth the claimed recitations of “a lancer removably mounted in said housing” in claim 1 and “a second compartment adapted to removably receive and store a lancer” in claim 24. [Emphasis added] While claim language is viewed broadly and the specification is looked to in order to further understand the claims, the instant disclosure does not establish that the lancer is “mounted in the housing” or “a second compartment on the housing to removably receive and store a lancer”.

In the Remarks section of the correspondence received on 3/14/2002, Applicant tries to assert that locking means 31 are a pair of hooks that are received in the housing. Locking means (31) are taught in the specification but are never further described to include hooks or any other structure. Additionally, the figures provide no further information regarding the locking means (31). The figures show element 31 as a quadrilateral shape, however one cannot tell if this structure extends from the lancer or is a recessed space (opening) that another member would

insert into. Furthermore, the quadrilateral shape could depict a “black box” element that depicts an entirely different intended structure.

Also, no reference to a compartment, or any similar language, that receives the lancer can be found in the specification. Additionally, the figures do not depict a compartment structure for receiving and storing the lancer. Conversely, the pictures more correctly show a concave portion on the lancer (surface with locking means 31: fig 3) that receives the housing (30). If anything, the specification sets forth and establishes the lancet receiving the housing in the concave portion of the lancet. See figure 3.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Castellano et al (USPN 5,728,074). Castellano discloses a housing (400), a monitor (442) integrally disposed in the housing, a medication delivery pen (22: see fig 25c), and a lancer (424) removeably secured to the housing. See figure 25a and 19:18-20:39. Castellano fails to include the delivery pen being removably mounted in the housing.

However, at the time of the invention, it would have been obvious to make the pen removeable from the housing. Making the pen removable is supported by the court and by common knowledge in the art.

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The court has held that if making a component of a device removable were desired then it would be obvious to make it so for that reason. *In re Dulberg*, 289 F.2d 522, 523, 129 USPQ 348, 349 (CCPA 1961) (The claimed structure, a lipstick holder with a removable cap, was fully met by the prior art except that in the prior art the cap is “press fitted” and therefore not manually removable. The court held that “if it were considered desirable for any reason to obtain access to the end of [the prior art’s] holder to which the cap is applied, it would be obvious to make the cap removable for that purpose.”). See M.P.E.P. 2144.04. In the instant case, one would desire removing the pen of Castellano upon failure of the pen to function while the rest of the system was still usable with the desire to replace the pen.

#### *Response to Arguments*

Applicant's arguments filed 2/7/05 have been fully considered but they are not persuasive. It is noted that even though the rejection above has been changed to a rejection under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, applicant's general arguments are responded to below.

Applicant main argument is that even though the specification does not disclose the locking means as hooks, the locking means 31 can only be interpreted as hooks based on the drawings. Regardless of whether the locking means 31 are hooks or any other type of protuberance the instant specification still does not provide a description for the claim language of “mounted in”. The lack of support results in the fact that the instant written disclosure and figures are completely silent as to the portion of the housing that, for lack of a more precise word, accepts the locking means 31 of the lancet. The side of the housing that connects with the

lancet is not described or shown in any fashion for one to understand the structure that connects with locking means 31. In order for the specification to establish "mounted in" one would need to be able either see from the drawings or read in the written disclosure that this is actually the case. Finally, as stated in the above rejection, the disclosure provides more support for the housing being mounted in the lancet due to the concave nature of the wall of the lancet that connects with the housing.

Additionally, applicant did not address the rejection citing the lack of support for "a second compartment". It is assumed that applicant acquiesces to the fact that the instant disclosure does not provide support for this limitation.

The Lav Declaration has been reviewed and is not found persuasive. The declaration asserts that even though the specification is lacking any description of the locking means one skilled in the art must conclude that whatever the structure of the locking means must be a hook or similar structure and enter into the housing. However, the locking means could just as likely be a magnetic element that attaches to the outside of the housing and does not enter the housing at all.

In response to applicant's argument that there is no motivation in the reference itself for the 103 rejection above, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the motivation is found generally available to one

of ordinary skill in the art. In the above rejection the motivation for removing the pen would be to replace a failed pen with a workable one. Applicant makes assumptions that a user would just replace the entire device. Applicant also sites as an example that if headphones on a stereo fail the user would simply listen using speakers and not rip out the jack. However, if the user had the ability to REPLACE the headphones, one could reasonably assume they would choose that option. The same thought process would be used by one skilled in the art to modify the device of Castellano and make the pen removable for replacement. By replacing the pen portion of the device one extends the life of the device thereby extending the original cash investment, a reasonable motivation for most reasonable people.

*Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Williams whose telephone number is 571-272-4970. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas D. Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Catherine S. Williams  
March 20, 2006